

Section 7



## **SECTION SEVEN**

### **SUMMARY**

As referenced in the clinical studies and documentation provided in Section Six, the creatine component of creatine ethyl ester HCL, is a well characterized dietary ingredient that has been used in the marketplace for muscular health for a significant amount of time. The ethanol component of creatine ethyl ester HCL is also well characterized and its safety for food use has long been established and recognized by FDA.

The level of use for creatine ethyl ester HCL for adults only will be at a level of 500 mg to 5 grams per day. Based on the fact that creatine ethyl ester HCL is more available to the body, its level of use will be well below the marketplace use of creatine monohydrate.

The ChemPharma Int'l. study that was coordinated with FDA clearly establishes that after oral administration of creatine ethyl ester HCL, it dissociates to creatine and ethanol. Based on the long history of use of both components of creatine ethyl ester HCL and the safety studies identified in Section Six, the distributor of creatine ethyl ester HCL considers their documentation sufficient to provide a reasonable basis for it being considered safe for use.